PB86-194495

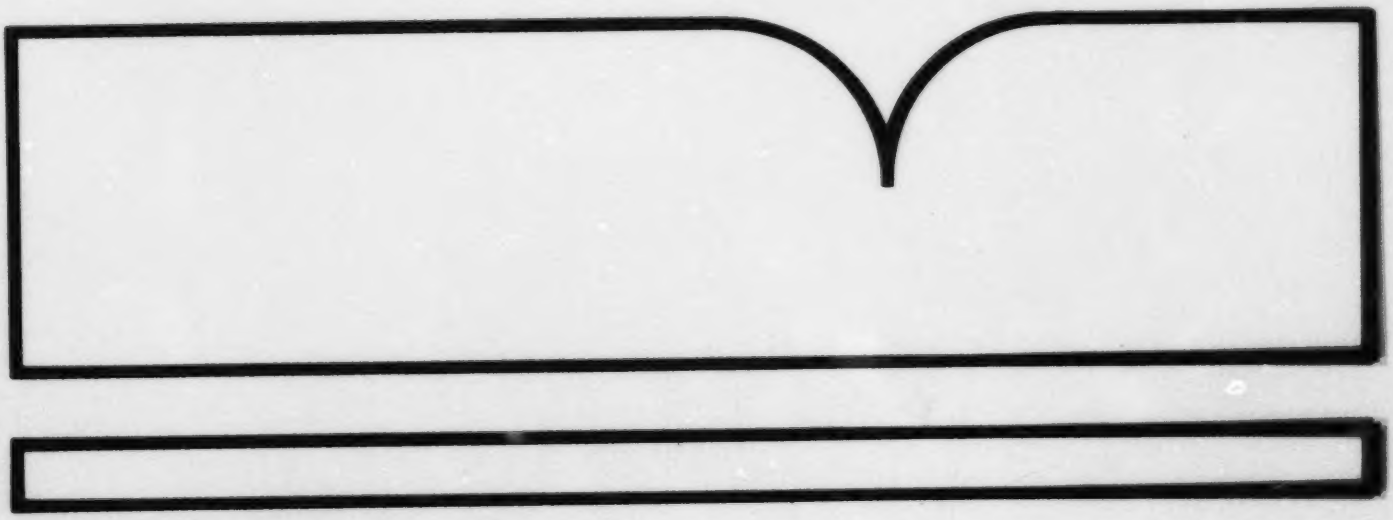
Widespread Outbreaks of Clam- and Oyster- Associated Gastroenteritis Role of Norwalk Virus

New York State Dept. of Health, Albany

Prepared for

Health Effects Research Lab.
Research Triangle Park, NC

1986



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1. REPORT NO. EPA/600/J-86/037	2.
	PB86-194495
4. TITLE AND SUBTITLE WIDESPREAD OUTBREAKS OF CLAM--AND OYSTER- ASSOCIATED GASTROENTERITIS: ROLE OF NORWALK VIRUS (Journal Version)	5. REPORT DATE 1986
	6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S) D. L. Morse et al. (11 authors total) (Full listing under item #16.)	8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS New York State Department of Health Albany, NY 12237 Univ. of Massachusetts School of Medicine; Dept. of Medicine, Worcester, MA 01605	10. PROGRAM ELEMENT NO. CBMC1A
	11. CONTRACT/GRANT NO. CR-812550
12. SPONSORING AGENCY NAME AND ADDRESS Health Effects Research Laboratory Office of Research and Development U.S. Environmental Protection Agency Research Triangle Park, NC 27711	13. TYPE OF REPORT AND PERIOD COVERED Journal Article
	14. SPONSORING AGENCY CODE EPA/600/11

15. SUPPLEMENTARY NOTES
P.O., Christon J. Hurst, MB, TMD, HERL, ORD, USEPA (CI); Citation: N. Engl. J. Med., Vol. 314, No. 11, 678-681, March 1986

16. ABSTRACT

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17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group

18. DISTRIBUTION STATEMENT	19. SECURITY CLASS (This Report)	21. NO. OF PAGES
Release to public	unclassified	6
	20. SECURITY CLASS (This page) unclassified	22. PRICE

EPA Form 2220-1 (Rev. 4-77) PREVIOUS EDITION IS OBSOLETE

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EPA/600/J-86/037
JOURNAL ARTICLE
March 13, 1986

WIDESPREAD OUTBREAKS OF CLAM- AND OYSTER-ASSOCIATED GASTROENTERITIS

Role of Norwalk Virus

DALE L. MORSE, M.D., JOHN J. GUZEWICH, M.P.H., JOHN P. HANRAHAN, M.D., RACHEL STRICOF, M.P.H., MEHDI SHAYEGANI, PH.D., RUDOLF DEIBEL, M.D., JOHN C. GRABAU, PH.D., NANCY A. NOWAK, M.A., JOHN E. HERRMANN, PH.D., GEORGE CUKOR, PH.D., AND NEIL R. BLACKLOW, M.D.

Abstract Consumption of raw shellfish has long been known to be associated with individual cases and sporadic outbreaks of enteric illness. However, during 1982, outbreaks of gastroenteritis associated with eating raw shellfish reached epidemic proportions in New York State. Between May 1 and December 31, there were 103 well-documented outbreaks in which 1017 persons became ill: 813 cases were related to eating clams, and 204 to eating oysters. The most common symptoms were diarrhea, nausea, abdominal cramps, and vomiting. Incubation periods were generally 24 to 48 hours long, and the duration of illness was 24 to 48 hours. Bacteriologic analyses of stool and shellfish specimens did not reveal a causative agent. Norwalk virus was implicated as the predominant etiologic agent by clinical features of the illness and by seroconversion and the formation of IgM antibody to Norwalk virus in paired serum samples from persons in five (71 percent) of seven outbreaks in which testing was done. In addition, Norwalk virus was identified by radioimmunoassay in clam and oyster specimens from two of the outbreaks. Determining the source of the shellfish was not always possible, but northeastern coastal waters were implicated. The magnitude, persistence, and widespread nature of these outbreaks raise further questions about the safety of consuming raw shellfish. (N Engl J Med 1986; 314:678-81.)

INGESTION of shellfish has been known for over 50 years to cause outbreaks of bacterial and viral enteric diseases.[1,2] Typhoid fever,[3] hepatitis A,[4-7] cholera,[8] and *Vibrio parahaemolyticus*[9] have long been associated with eating raw clams and oysters. More recently, outbreaks of gastroenteritis due to non-01 *Vibrio cholerae*,[10] Norwalk virus,[11,12] campylobacter,[13] and "small round structured viruses"[14] have been associated with consumption of raw shellfish.

Unlike previous outbreaks of raw-shellfish–associated gastroenteritis, which have generally been infrequent and sporadic, the outbreaks summarized here were frequent and widespread events in which Norwalk virus had a major etiologic role.

METHODS

During 1982, in response to numerous reports of shellfish-associated illness, the New York State Health Department established procedures for systematic collection of epidemiologic data. A shellfish-related outbreak was defined as an incident in which gastrointestinal symptoms (nausea, vomiting, diarrhea, or abdominal cramps) developed in two or more persons within 72 hours after they had eaten clams or oysters that were implicated as the source of illness. Epidemiologic investigations were conducted according to standard techniques for evaluating foodborne outbreaks.[15] Persons representative of those who attended events at which suspect shellfish were eaten were interviewed to obtain basic demographic information, food-consumption histories regarding all foods served, and the date of onset, duration, and type of symptoms.

Stool specimens from some symptomatic persons were tested for enteric pathogens, including salmonella, shigella, campylobacter, yersinia, *Staphylococcus aureus*, *Bacillus cereus*, *Clostridium perfringens*, and vibrio bacteria and enteroviruses, rotaviruses, and adenoviruses. Leftover shellfish were tested for the same pathogens and for total and fecal coliform counts.

Paired serum samples from subjects in some outbreaks statistically associated with shellfish consumption were tested for total serum antibody to Norwalk virus by means of radioimmunoassay and for IgM-specific Norwalk antibody by methods previously described.[16,17] Stool and shellfish specimens were tested for Norwalk virus antigen by radioimmunoassay. Shellfish extracts were prepared as 5 percent homogenates in veal-infusion broth with 0.5 percent bovine serum albumin and were tested by radioimmunoassay in the manner previously described for stool extracts.[16]

Attempts were made to identify the source of implicated clams and oysters by using tags of shellfish shippers in combination with records of distributors to track the origins of the shellfish.

RESULTS

Of several hundred incidents reported during 1982, 103 in 21 counties were sufficiently documented so that they met the criteria for classification as a shellfish-associated outbreak. The events preceding the illnesses were attended by more than 6000 persons, of whom 2319 were interviewed. Of those interviewed, 1017 (44 percent) had become ill — 813 after having eaten clams, and 204 after having eaten oysters. These outbreaks occurred during distinct "summer" and "winter" periods (Fig. 1).

Summer Outbreaks

Ten upstate counties reported 22 summer outbreaks of clam-related illness: 17 involved gastroenteritis, 1 involved hepatitis A, and 4 involved both illnesses. Of 3372 persons attending the events, 443 of 1241 interviewed had had gastrointestinal illnesses (Table 1). Overall attack rates ranged from 56 percent among persons eating raw clams or both raw and steamed clams, to 26 percent among those eating steamed clams, to 3 percent among those not eating any clams.

In 16 outbreaks there was a statistically significant association ($P<0.05$) between consumption of raw clams and illness. Detailed questionnaires for 1058 persons in 14 of these 16 outbreaks showed that 357 (34 percent) had one or more gastrointestinal

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Supported in part under a cooperative agreement (CR8-12550-01) with the U.S. Environmental Protection Agency and under a contract (DAMD-17-83-C-3087) from the U.S. Army Medical Research and Development Command.

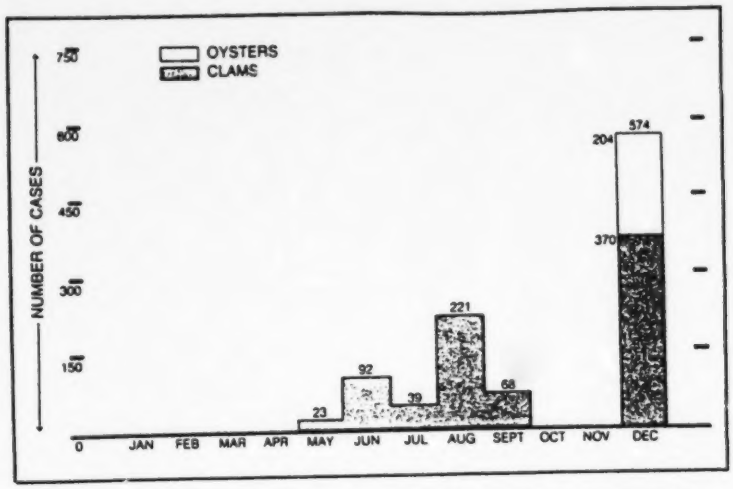

Figure 1. Well-Documented Cases of Shellfish-Associated Gastroenteritis, New York State, 1982.

symptoms (nausea, vomiting, diarrhea, or abdominal cramps). The 14 outbreaks had generally similar epidemiologic features, but the specific features of individual outbreaks varied. Overall symptoms included diarrhea (84 percent), abdominal cramps (58 percent), nausea (52 percent), and vomiting (30 percent); fever was reported least frequently (19 percent). Among 310 persons with known incubation periods, symptoms developed in 97 percent between 12 and 72 hours after exposure (mean and median, 40). Symptoms persisted for less than 48 hours in 82 percent of persons reporting on their duration, but lasted for up to one week in 5 percent.

Attack rates were comparable among male (34 percent) and female (34 percent) subjects and did not differ according to age group. There was a dose–response relation between the number of raw clams consumed and the risk of gastroenteritis, but not between the number of steamed clams eaten and illness. Attack rates were 35 percent (23 of 66) among persons consuming 1 to 3 raw clams, 50 percent (52 of 103) among those consuming 4 to 9, and 59 percent (238 of 405) among those consuming 10 or more (chi-square = 13.92, $P<0.001$).

Ten of 207 persons consuming clams in five of the early outbreaks had hepatitis A infection 21 to 39 days later and had no other known risk factors. Seven had gastroenteritis shortly after eating. Eight had consumed raw clams, and two had eaten steamed clams. Concurrently, authorities in one county where clams were harvested noted a doubling of cases of hepatitis A. Forty of the first 74 cases in 1982, or 54 percent, were related to clams, as compared with only 12 percent from 1979 to 1981. These findings resulted in recommendations for the prophylactic use of immunoglobulin in subsequent outbreaks.

Clams implicated in 13 of these outbreaks were traced to Rhode Island waters, and in 2 outbreaks to Massachusetts. In six of the outbreaks, several states and a province of Canada were possible sources: Rhode Island, six outbreaks; New York, five; North Carolina, two; Prince Edward Island, two; and Massachusetts, one.

Winter Outbreaks

During December, 13 counties reported 81 outbreaks of shellfish-related illness. Of these outbreaks, 35 involved enough people so that a significant association ($P<0.05$) could be shown between consumption of raw shellfish and illness. When the 81 outbreaks were consolidated according to common shellfish source into 16 outbreaks, raw clams were statistically associated with illness in 15 of them.

Of the 1078 persons interviewed, 574 (53 percent) had had gastroenteritis; the attack rate among persons consuming raw shellfish was 92 percent. Symptoms showed little variation by outbreak and included nausea (75 percent), diarrhea (73 percent), abdominal cramps (63 percent), and vomiting (53 percent). Incubation periods ranged from 24 to 40 hours (mean, 31). Symptoms lasted from 18 to 48 hours (mean, 33).

Oysters implicated in 10 of the 11 oyster-associated outbreaks originated in Massachusetts. These oysters had been harvested by an unlicensed Massachusetts digger, who obtained them illegally from polluted waters closed to harvesting. The source of clams was

Table 1. Summary of Shellfish-Associated Outbreaks of Gastroenteritis, New York State, 1982.*

	"Summer" Outbreaks	"Winter" Outbreaks
No. of counties with outbreaks	10	13
No. of outbreaks	22	81
No. of people		
Attended event	3372	~3000
Interviewed	1241	1078
With gastroenteritis	443 (36%)	574 (53%)
With hepatitis	10	0
Attack rates		
Raw clams only	56%	92%†
Raw and steamed clams	56%	
Steamed clams only	26%	NA‡
No clams	3%	4%
Symptoms		
Diarrhea	84%	73%
Abdominal cramps	58%	63%
Nausea	52%	75%
Vomiting	30%	53%
Fever	19%	26%
Mean incubation period	40 hr	33 hr
Mean illness duration	41 hr	31 hr

*Detailed information on individual outbreaks is available from the authors upon request.
†The raw-clams-only and the raw-and-steamed-clams categories were combined.
‡Data not available.

primarily New York waters, with six shippers implicated in more than 75 percent of the outbreaks.

Laboratory Studies

Stool specimens from hundreds of ill persons were tested at local laboratories throughout New York, but no bacterial pathogens were identified. Testing at the state laboratory of specimens from 19 outbreaks did not reveal a causative agent. With rare, isolated exceptions, the 56 stool and 36 shellfish specimens were negative for bacterial and viral pathogens; all 36 clam and oyster specimens had total and fecal coliform counts within acceptable standards. Although enterotoxigenic *Escherichia coli* was not tested for directly, total coliform counts were far below the accepted infectious dose for this organism.[18]

One hundred fourteen serum, stool, and shellfish specimens were analyzed for evidence of Norwalk-virus infection in seven outbreaks — i.e., four summer and three winter outbreaks (Table 2). Six outbreaks involved clams, and one involved oysters (Outbreak W1). All seven outbreaks had a significant association between consumption of raw shellfish and gastroenteritis, but differed in symptoms, incubation periods, and durations of illness (in particular, Outbreaks S12 and S22). Acute-phase serum specimens were drawn within one week of exposure (except for Outbreak W47, in which specimens were drawn 11 to 13 days after exposure), and convalescent-phase blood specimens were drawn three or more weeks after exposure and the onset of illness.

Fifteen paired serum samples from persons in five of the seven outbreaks showed seroconversion (fourfold or higher rises in total serum antibody titer) to Norwalk virus. Seroconversion had occurred in at least half the persons in four of the five outbreaks who were tested, but in only 1 of 14 persons in the fifth outbreak (W47). However, the acute-phase specimens in the fifth outbreak were drawn late, and the titers against Norwalk virus were extremely high (up to 1:51,200) in all but one patient. Marked levels of IgM antibodies to Norwalk virus, indicative of recent infection with the virus,[17] were detected in 22 of 25 serum samples tested. These 25 samples included all 10 from Outbreak W47 that had shown high acute-phase titers for antibody to Norwalk virus without seroconversion.

Only four stool specimens from Norwalk-virus–related outbreaks were available for testing, and the virus was not detected by radioimmunoassay in any. Four of the six shellfish specimens from two outbreaks that were tested were positive for Norwalk virus — one outbreak involving clams, and one involving oysters.

Discussion

The magnitude and widespread nature of these shellfish-associated outbreaks of gastroenteritis point up the hazards associated with consumption of this food. Illness was usually associated with eating raw clams or oysters, but there was an unexpectedly high attack rate (26 percent) among persons who ate only steamed clams at the same events. This demonstrates that under practical field conditions, temperatures used to steam clams are often insufficient to inactivate pathogens and to eliminate the risk of illness. At least one study has shown that 7 to 13 percent of poliovirus organisms added to oysters survive 8 to 30 minutes when cooked according to various commonly used methods.[19] Another study has reported that it takes four to six minutes of steaming for the internal temperature of soft-shell clams to reach 100°C, but only 60 seconds for their shells to open, which is the standard commonly used to determine whether shellfish have been sufficiently cooked.[20] Although it may not be necessary to cook clams until they "turn to rubber," as some persons suggest, more thorough cooking is certainly required.

The etiologic agent in these outbreaks was initially unknown but appeared to be viral, on the basis of the incubation period (24 to 48 hours), duration of illness (24 to 48 hours), self-limiting nature of the symptoms, and negative findings of bacteriologic studies.[21] In addition, the findings in 80 percent of the outbreaks (76 of the 95 with sufficient data) were consistent with previously published clinical and epidemiologic criteria for a Norwalk-virus–like pattern.[22] Subsequent laboratory studies confirmed a major etiologic role for

Table 2. Epidemiologic Features and Laboratory Results in Seven Outbreaks Tested for Norwalk Virus, New York State, 1982.

Outbreak No.	Date Clams Eaten	Symptoms					Mean Incubation	Mean Duration	Positivity for Norwalk Virus			
		Nausea	Diarrhea	Cramps	Vomiting	Fever			Sero-conversion	IgM+ serum	Stool*	Shellfish
		percent of ill persons affected					*hr*	*hr*	*specimens positive/specimens tested*			
S12	7/11	0	86	86	0	14	28	67	0/8	—	0/4	—
S22	9/1	55	66	65	25	23	49	24	0/4	—	—	—
S16	8/26	33	89	37	16	9	40	41	2/4	2/2	—	—
S17	8/27	55	85	55	35	13	43	50	4/8	4/4	—	—
W1	12/19	75	70	52	48	31	32	31	6/8	5/6	0/1	2/3
W38	12/25	70	83	49	70	30	40	32	2/4	1/2	0/3	2/2
W47	12/11	88	96	72	60	36	40	36	1/14†	10/11	—	0/1

*Only one stool specimen was available from a person who seroconverted to Norwalk virus.

†Acute-phase serum samples were collected late (11 to 13 days after exposure).

Norwalk virus. In five of seven outbreaks, seroconversion to Norwalk virus or positivity for specific IgM antibody to the virus (or both) were present, and four of six shellfish specimens, including both clams and oysters, showed positivity for Norwalk virus on radioimmunoassay. The IgM titers were confirmatory and ruled out any potential effect that immunoglobulin administration may have had on total serum antibody titers. Norwalk virus was not detected in stool, but this is not surprising, given the paucity of specimens and the inclusion of only one sample from a person with seroconversion. All three "winter" outbreaks were linked to Norwalk virus. The similarity of epidemiologic features, symptoms (with a high rate of vomiting), and shellfish sources in the winter outbreaks suggests that most were related to the virus. Only two of four outbreaks during "summer," in which there was greater variation in epidemiologic features and shellfish sources, were positive for Norwalk virus. This suggests that other pathogens were also involved during the "summer" and may explain the differences between the summer and winter outbreaks in upper gastrointestinal tract symptoms, incubation period, and illness duration.

The sources of the shellfish were difficult to trace because of inadequacy or absence of shipping tags and the potential for illegally harvested clams to be mixed in with legally harvested clams. Despite these limitations, most outbreak-related shellfish were traced to coastal waters of several northeastern states, suggesting a widespread problem. Contamination of harvest beds by heavy spring rains and subsequent runoff may explain some of these outbreaks. However, the continuation of outbreaks during periods without flooding suggests endemic contamination.

Although recent shellfish-associated outbreaks have not reached the epidemic proportions of 1982, outbreaks in several northeastern states during 1983, 1984, and 1985 (including 59 outbreaks resulting in 888 documented cases of illness within New York State alone) demonstrate that the problem is continuing. Until effective control measures are developed, the public should be warned that consumption of raw clams and oysters poses a risk of enteric illness, particularly Norwalk virus–like gastroenteritis.

We are indebted to the staffs of the following organizations: the Health Departments of Albany, Broome, Chemung, Fulton, Genesee, Hamilton, Kings, Monroe, Montgomery, Nassau, Oneida, Onondaga, Queens, Rensselaer, Saratoga, Schenectady, Schoharie, Suffolk, Ulster, Warren, and Westchester Counties: the district, regional, and central offices of the New York State Health Department; the New York State Departments of Agriculture and Markets and Environmental Conservation and similar agencies in several northeastern states; and the Centers for Disease Control and the Food and Drug Administration.

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